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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,074	10/12/2001	Richard Boyd	156857-0042	1931
29000	7590	10/03/2003		
IRELL & MANELLA LLP 1800 AVENUE OF THE STARS SUITE 900 LOS ANGELES, CA 90067				
EXAMINER BELYAVSKYI, MICHAEL A				
ART UNIT		PAPER NUMBER		
1644				

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/977,074	BOYD, RICHARD	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michail A Belyavskyi	1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 38-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 38-81 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicant's amendments, filed 07/07/03 is acknowledged.

*Claims 38-81 are pending.*

### ***Restriction Requirement***

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
- I. Claims 38-48, 50-52, 61, 62, 64-74 and 79 drawn to a method for determining susceptibility of a patient's thymus to activation and the use of an assay selected from the group recited in claim 79, including identification of one or more thymic factors and wherein disruption of sex steroid mediated signaling includes blocking of one or more sex steroid receptors within the patient's thymus, classified in Class 424, subclass 184.1; Class 435, subclass 7.1.
  - II. Claims 38-48, 50-52, 60, 62, 63 and 79 drawn to a method for determining susceptibility of a patient's thymus to activation and the use of an assay selected from the group recited in claim 79, including identification of one or more thymic factors wherein disruption of sex steroid mediated signaling is by chemical castration, classified in Class 424, subclass 184.1; Class 435, subclass 7.1.
  - III. Claims 38-54, 57-59, 61, 62, 64-74 and 79 drawn to a method for determining susceptibility of a patient's thymus to activation and the use of an assay selected from the group recited in claim 79, including identification of one or more indicators of thymic function and wherein disruption of sex steroid mediated signaling includes blocking of one or more sex steroid receptors within the patient's thymus, classified in Class 424, subclass 184.1; Class 435, subclass 7.1.
  - IV. Claims 38-54, 57-60, 62, 63 and 79 drawn to a method for determining susceptibility of a patient's thymus to activation and the use of an assay selected from the group recited in claim 79, including identification of one or more indicators of thymic function and wherein disruption of sex steroid mediated signaling is by chemical castration, classified in Class 424, subclass 184.1; Class 435, subclass 7.1.

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- V. Claims 38-59, 61,62, 64-74 and 79 drawn to a method for determining susceptibility of a patient's thymus to activation and the use of an assay selected from the group recited in claim 79, including identification of one or more thymic function and including a step of monitoring one or more population of T cells and wherein disruption of sex steroid mediated signaling includes blocking of one or more sex steroid receptors within the patient's thymus , classified in Class 424, subclasses 184.1 and 93.1; Class 435, subclass 7.1.
- VI. Claims 38-60, 62, 63 and 79 drawn to a method for determining susceptibility of a patient's thymus to activation and the use of an assay selected from the group recited in claim 79, including identification of one or more thymic function and including a step of monitoring one or more population of T cells and wherein disruption of sex steroid mediated signaling is by chemical castration , classified in Class 424, subclasses 184.1 and 93.1; Class 435, subclass 7.1.
- VII. Claims 38-59, 61,62, 64-79 , drawn to a method for determining susceptibility of a patient's thymus to activation and the use of an assay selected from the group recited in claim 79, including identification of one or more thymic function and including a step of monitoring one or more population of T cells and including a step of isolating the DNA of the cells and performing PCR on the isolated DNA and wherein disruption of sex steroid mediated signaling includes blocking of one or more sex steroid receptors within the patient's thymus , classified in Class 424, subclasses 184.1 and 93.1; Class 435, subclass 7.1 and 91.2.
- VIII. Claims 38-60, 62, 63 and 75-79, drawn to a method for determining susceptibility of a patient's thymus to activation and the use of an assay selected from the group recited in claim 79, including identification of one or more thymic function and including a step of monitoring one or more population of T cells and including a step of isolating the DNA of the cells and performing PCR on the isolated DNA and wherein disruption of sex steroid mediated signaling is by chemical castration, classified in Class 424, subclasses 184.1 and 93.1; Class 435, subclass 7.1 and 91.2.
- IX. Claims 80 and 81 , drawn to a kit for use in determining the susceptibility of a thymus to activation, classified in Class 435, subclass 810.

4. Groups I - VIII are different methods. These invention are different with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

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5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

In addition, Groups VII, VIII and IX reads on and or uses patentable distinct sequences, for example recited in claims 77 or 81. Each sequence is patentably distinct because they are unrelated sequences and further restriction is applied to each group. For each elected group drawn to or using nucleotide sequence, the Applicant are required to elect a single sequence (See MPEP 803.04).

In view of limited office resources, only a single nucleic or amino acid sequence will be examined in this application. In addition, to the specific selected sequence, those sequences which are patentably indistinct from the selected sequences will be also examined.

Examination will be restricted to only the elected sequences.

### **Species Election**

6. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

7. If Group III, IV, V, VI, VII or VIII is elected, applicant is required to elect a specific method for determining susceptibility of a patient's thymus to activation wherein a specific thymopoietic hormone is selected from the group recited in claim 54.

These species are distinct because a specific method for determining susceptibility of a patient's thymus to activation wherein a specific thymopoietic hormone is selected from the group recited in claim 54 differ with respect to the thymopoietic hormone; thus each specific method employing a specific thymopoietic hormone represents patentably distinct subject matter. Furthermore, the examination of specific thymopoietic hormone such as ones recited in the Claims 54, in the method for method for determining susceptibility of a patient's thymus to activation would require different searches in the scientific literature.

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In addition to the election of a specific thymopoietic hormone,

8. If Group I, III, V, or VII is elected, applicant is required to elect a specific method for determining susceptibility of a patient's thymus to activation, wherein a specific sex steroid blocker is, for example selected from the Group recited in claims 65 or 68 or 69 or 74.

These species are distinct because a specific method for determining susceptibility of a patient's thymus to activation, wherein a specific sex steroid blocker is, for example selected from the Group recited in claims 65 or 68 or 69 or 74 differ with respect to the use of specific sex steroid blocker; thus each specific method employing a specific sex steroid blocker represents patentably distinct subject matter. Furthermore, the examination of specific sex steroid blocker such as ones recited in the Claims in claims 65 or 68 or 69 or 74 in the method for determining susceptibility of a thymus in a patient to activation would require different searches in the scientific literature.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskyi, Ph.D.  
Patent Examiner  
Technology Center 1600  
September 30, 2003

  
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